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Remarks

Applicant has canceled claims 31-39 and 41 without prejudice or disclaimer, and amended claim 26.

Claims 22-30 and 40 are pending. The Examiner has withdrawn claim 40; Applicant again notes that claim 40 should be rejoined and examined upon the allowance of claim 22 pursuant to the rejoinder procedures. See M.P.E.P. § 821.04.

I. Objection to the Specification

The Examiner has objected to the specification for not including the updated status of nonprovisional parent Application No. 10/084,205 in the first line. In response, Applicant has amended paragraph 0001 both to update the status of the parent application and to comply with recent Office guidance on the formatting of benefit claims, thereby obviating the Examiner's objection. Thus, Applicant respectfully requests that the Examiner reconsider and withdraw the instant objection.

II. Rejection of Claims 26 and 35 Under 35 U.S.C. §§ 112, 2nd Paragraph & 101

The Examiner has rejected claims 26 and 35 as allegedly indefinite and reading on non-statutory subject matter. In particular, the Examiner requests that the words "isolated" and "fully" be added to the claim.

In response, Applicant notes that claim 35 has been canceled without prejudice or disclaimer, thereby obviating any rejection of the claim. Further, although Applicant does not acquiesce to the rejection, claim 26 has been amended as requested by the Examiner, thereby obviating the rejection. Thus, Applicant respectfully requests that the Examiner reconsider and withdraw the instant rejection.

III. Rejection of Claims 31-39 Under 35 U.S.C. § 102

The Examiner has rejected claims 31-39, or a subset of those claims, under 35 U.S.C. § 102 as allegedly anticipated by Lowe, Nicola, Wallis, and Kunsch.

In response, claims 31-39 have been canceled without prejudice or disclaimer, thereby obviating any rejection of those claims. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the instant rejection.

IV. Rejection of Claims 31-39 Under 35 U.S.C. § 103

The Examiner has rejected claims 22-39 under 35 U.S.C. § 103(a) as allegedly unpatentable over any one of Lowe, Nicola, Wallis, or Kunsch.

With respect to claims 31-39, as noted above, these claims have been canceled without prejudice or disclaimer, thereby obviating any rejection of those claims.

With respect to claims 22-30, to establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings, as well as a reasonable expectation of success. The prior art reference(s) must also teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. See *In re Vaack*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991); see also M.P.E.P. § 2142.

With respect to a suggestion in the prior art, "[t]he initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done." M.P.E.P. § 2142 at 2100-128. Moreover, there are only three possible sources for such a suggestion: "the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998); see M.P.E.P. § 2143.01.

In the instant case, the Examiner has admitted that the sequences of the cited references are not identical to the claimed polynucleotide. See Office Action at pages 4-6 and attached alignments. Thus, the prior art references cannot *prima facie* teach or suggest all the claim limitations. Moreover, the alignments provided by the Examiner highlight these structural differences between the claimed polynucleotide and the prior art.

Further, the Examiner has not shown any suggestion or motivation for one skilled in the art to modify the sequences in the cited references to arrive at the specific species claimed in the instant claims. Although the Examiner asserts that, "The slight differences in nucleotide sequence [are] due to obvious conservative substitutions which do not change the functionality of the nucleotide sequence," (*Id.* at pages 6-7), the Examiner has not provided any support from the teachings of the prior art or the knowledge of persons of ordinary skill in the art for that assertion.

Indeed, the Examiner's position is inconsistent with controlling Federal Circuit precedent and PTO guidance on the evaluation of species claims. In *In re Deuel*, the Federal Circuit held that a "*prima facie* case of unpatentability requires that the teachings of the prior art suggest the

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claimed compounds to a person of ordinary skill in the art." 51 F.3d 1552, 1557 (1995). The court continued:

A prior art disclosure of the amino acid sequence of a protein does not necessarily render particular DNA molecules encoding the protein obvious because the redundancy of the generic code permits one to hypothesize an enormous number of DNA sequences coding for the protein. No particular one of these DNAs can be obvious unless there is something in the prior art to lead to the particular DNA and indicate that it should be prepared." *Id.* at 1558-59 (emphasis added).


See also M.P.E.P. § 2144.08. Thus, Applicant respectfully asserts that the Examiner has not presented a proper *prima facie* case of unpatentability under 35 U.S.C. § 103(a), as the Examiner has not shown why one of skill in the art would be led to the particular species claimed by Applicant from the disclosure of the species in the prior art. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the instant rejection.

Conclusion

In view of the foregoing remarks, Applicant believes that this application is now in condition for allowance, and an early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the allowance of this application. If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the fee should also be charged to our Deposit Account.

Dated: September 27, 2004

Respectfully submitted,

By 

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CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. § 1.8

1. Fax Cover Sheet
2. Response And Amendment Under 37 C.F.R. § 1.111

I hereby certify that the above-listed correspondence is being facsimile transmitted to the United States Patent and Trademark Office on September 27, 2004.



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